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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,481	09/24/2001	Joseph R. Byrum	38-21(15367)C	6590

7590 04/26/2004
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,481	Applicant(s) BYRUM ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Response filed 02/18/2004 is acknowledged. Claim 8 is amended. Claims 9-13 are added. Claims 8-13 are pending.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10,13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 10,13 introduce new matter as they address nucleic acid SEQ ID No. 5278 having a region having a single nucleotide polymorphism. Specification does describe on pages 23-26 general aspects of using SNPs, but does not describe that the nucleic acids of this invention are having a region having a single nucleotide polymorphism.

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Claim Rejections - 35 U.S.C. § 101/ 112-1

3. Claims 8-13 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility. The rejection is applied for the reasons of record as applied to claim 8 and further in view of the following.

Applicant argues that that SEQ ID No. 5278 is derived from library SOYMON31. The description on p. 86 addressed by applicant refers to more than 10000 of polynucleotides and does not provide any substantial or specific utility to any of them. The potential specific utilities suggested by Applicant (identifying polymorphisms, determining plant traits, DNA mapping) are an invitation to do further research to search for a specific and substantial utility for each polynucleotide claimed. No particular activity, function, or disease link is ascribed to the claimed polynucleotide SEQ ID No. 5278. General uses of polynucleotides set forth in the specification, as filed, include acquiring genes, identifying polymorphisms, determining plant traits, and DNA mapping. None of these is considered to be specific and substantial in view of the limited information provided in the specification. No plant traits are attributed to SEQ ID No. 5278. No complete gene is disclosed for SEQ ID No. 5278. No DNA maps or chromosomal locations are identified. No polymorphisms are identified. The specification does not disclose how a polymorphism would be recognized by those of

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ordinary skill in the art given the incomplete sequences disclosed. One of ordinary skill in the art would have reason to doubt that SEQ ID No. 5278 was full length based upon the short length of the claimed SEQ ID NO 5278. Further research and experimentation would be required to identify a full length sequence that encoded a full-length protein, to characterize the chromosomal location, to determine the presence of polymorphisms, and to determine any associated plant traits. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Further, no readily apparent well-established utility for any the polynucleotide is set forth in the specification. Applicant is reminded of *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689 (1966), which stated that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As set forth above, the myriad of asserted utilities are general utilities applicable to a broad class of compounds, and do not meet the specific and substantial criteria for utility under the present guidelines.

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Applicant further argues that certain other types of inventions, such as microscopes or golf clubs, would not be patentable; however, the utility of those apparatus are not sufficiently related to the isolated polynucleotides under examination such that any definite conclusions as to utility can be drawn. Applicant notes that "An important utility of a microscope resides in its use to identify..." however, whether that utility is the only utility or the only patentable utility is not clear, and not at issue here.

4. Claims 1, 10-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion.

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

April 23, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

